MICHELE A. DIMARTINO THE MILLER FIRM, LLC 2 Bala Plaza, Suite 603 Bala Cynwyd, PA 19004 Telephone: (610) 660-0622

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

George Dawkins, Jr.,) CIVIL ACTION NO.:
Plaintiff,) 3:07-cv-01186 (FLW-TJB)
vs.)) FIRST AMENDED COMPLAINT) AND JURY DEMAND
Bristol-Myers Squibb Company,)
Sanofi-Aventis U.S. L.L.C.,)
Sanofi-Aventis U.S., Inc., and)
Sanofi-Synthelabo, Inc.,)
)
Defendants.)

COMES NOW, the Plaintiff, George Dawkins, Jr., bringing this action for injuries and damages suffered as a result of ingesting the drug Plavix. In support, Plaintiff alleges the following.

I. PARTIES

- 1. Plaintiff, George Dawkins, Jr., is a natural person currently residing, and at all times material to this complaint, residing at 554 West Avenue, Apartment #4, Tallmadge, Ohio.
- 2. Defendant, Bristol-Myers Squibb Company (hereinafter referred to as "BMS") is a pharmaceutical manufacturing and marketing company that partners with Sanofi-Aventis (now Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc.) to

manufacture and market Plavix in the United States. Bristol-Myers Squibb Company has its headquarters at 345 Park Avenue, New York, New York 10154-0037.

- 3. Defendant, Sanofi-Aventis U.S. L.L.C. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S. L.L.C. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.
- 4. Defendant, Sanofi-Aventis U.S., Inc. is a subsidiary of the French pharmaceutical company, Sanofi-Aventis, which partners with Defendant Bristol-Myers Squibb Company to manufacture and market Plavix in the United States. The American base for Sanofi-Aventis U.S., Inc. is 400 Somerset Corporate Boulevard, SC4-310A, Bridgewater, New Jersey, 08807-0912.
- 5. Defendant, Sanofi-Synthelabo, Inc. is a Delaware corporation with its commercial headquarters at 90 Park Avenue, New York, New York 10016. Sanofi-Synthelabo Inc. did business as Sanofi Pharmaceuticals, Inc. and was the sponsor for the drug application for Plavix. Sanofi-Synthelabo, Inc. is an affiliate of Sanofi-Aventis, Sanofi-Aventis U.S. LLC and Sanofi-Aventis U.S., Inc. that was instrumental in bringing Plavix to market.
- 6. The three Sanofi Defendants—Sanofi-Aventis U.S. LLC, Sanofi-Aventis U.S., Inc. and Sanofi-Synthelabo, Inc.—will be collectively referred to as "Sanofi" in this Complaint.

II. JURISDICTION AND VENUE

7. This Court has jurisdiction pursuant to 28 United States Code § 1332,

because of the diversity of citizenship among the parties and because the amount in controversy exceeds Seventy-Five Thousand Dollars (\$75,000.00), exclusive of interest and costs.

- 8. Venue in this action properly lies in the District of New Jersey in that the Sanofi Defendants reside in this district.
- 9. This action is brought under the Ohio Products Liability Act, ("Products Liability Act"), the Ohio Consumer Sales Practices Act, ("OCSPA"), and the common law of the State of Ohio, to recover damages and other relief, including the costs of suit and reasonable attorneys' and expert fees, to compensate the Plaintiff for injuries the Plaintiff has sustained as a result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling and/or the sale of Plavix.

III. FACTS

- 10. This is an action for damages suffered by Plaintiff as a direct and proximate result of the Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of Plavix.
- 11. At all material times, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by the Defendants.
- 12. The Sanofi Defendants and BMS co-developed Plavix, applying in April 1997 for a rare, priority regulatory review by the FDA (Food and Drug Administration), which cleared the way for the Defendants to bring Plavix to market in November 1997.

- 13. The rush to obtain FDA approval of Plavix is indicative of the Defendants' emphasis on marketing and profit making over patient safety.
- 14. Plavix was heavily marketed directly to consumers through television, magazine and Internet advertising. It was touted as a "super-aspirin," that would give a person even greater cardiovascular benefits than a much less expensive, daily aspirin, while being safer and easier on a person's stomach than aspirin. Those assertions have proven to be false.
- 15. The truth is, that BMS and Sanofi always knew, or if they had paid attention to the findings of their own studies, should have known, that Plavix was not more efficacious than aspirin to prevent heart attacks and strokes. More importantly though, Defendants knew or should have known that when taking Plavix, the risk of suffering a heart attack, stroke, internal bleeding, blood disorder, or death far outweigh any potential benefit.
- 16. Still, BMS and Sanofi continued to exaggerate the results of their own studies and to make false statements in their advertising and promotional materials for the purpose of increasing their profit from Plavix sales.
- 17. The profit at stake for the Defendants is enormous. By way of illustration, in 2005, Plavix, was the sixth top selling drug in the United States and the Defendants enjoy annual sales of Plavix totaling \$3,800,000,000.00 (3.8 Billion Dollars).
- 18. BMS and the Sanofi Defendants repeatedly thwarted the law and their duty to tell the public the truth about the drug they were over-promoting for profit. The FDA issued numerous letters insisting these Defendants stop their misleading, over-promoting practices.

- 19. As examples, in 1998, the FDA requested the Defendants stop promoting Plavix for off-label use in patients receiving arterial stents. In the same reprimand, the FDA noted that not only were the Defendants marketing Plavix to physicians for a treatment for which it had not been approved, but also were recommending that a non-FDA-approved dosage nearly four (4) times that of other applications be given.
- 20. That same FDA warning criticized the Defendants' attempts at overpromotion of Plavix for unapproved use for lacking fair balance and failing to disclose
 any of the risks associated with its use. In particular, the FDA criticized that the
 Defendants were claiming to physicians, in their promotional letter, that Plavix was safe
 for use with other drugs. This, said the FDA, was overstating the safety profile of Plavix.
 In particular, its safety when combined with aspirin (known as "dual therapy") had not
 been established, yet Defendants were making a claim that the dual combination therapy
 of aspirin plus Plavix was safe. This claim has now been proven to be untrue in a recent
 study called CHARISMA (the Clopidogrel for High Atherothrombotic Risk and Ischemic
 Stabilization, Management, and Avoidance trial), which was reported on in *The New*England Journal of Medicine, April 20, 2006.
- 21. Again in 1998, the FDA issued a letter demanding the Defendants immediately cease distribution of advertising materials that claimed that Plavix has been proven to be more effective than aspirin. The FDA criticized this marketing ploy as an overstatement of efficacy that is lacking in fair balance and unsubstantiated.
- 22. Undaunted, the Defendants were back in the business of hiding bad facts about their drug and fabricating more favorable information so they could sell large quantities of Plavix and make giant corporate profits. In 2001, the FDA was again forced

to order Defendants to immediately cease distribution of promotional material that made unsubstantiated claims about Plavix and was misleading. Specifically, the Defendants' promotional material misled consumers about their own study, called CAPRIE, (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events). While the Defendants' trumped-up promotional material claimed that Plavix was 19.2% better than Aspirin, the actual findings of the CAPRIE study were that Plavix was not proven to be significantly more effective than aspirin—providing a 2.9% reduction in ischemic events versus a 3.47% reduction of ischemic events for the study participants who had been given aspirin. Defendants again claimed that the use of Plavix combined with aspirin was safe and effective, and again, the FDA forced Defendants to stop saying that because it had not been proven to be true.

- 23. In addition to misinforming physicians and the public through their advertising to consumers and promotional materials for doctors, Defendants' drug representatives have also misinformed physicians about the proper types of patients who should be given Plavix, the duration of its proper usage, and the applications for which it is safe and FDA approved.
- 24. Defendants, through their drug representatives, and their promotional efforts, have encouraged physicians to prescribe Plavix to a broad population of people who would receive the same therapeutic benefit from aspirin alone, (without risking death) and to use Plavix for unapproved applications.
- 25. The result is that physicians are prescribing Plavix to people who could be cheaply and effectively protected against ischemic events by a simple aspirin, to pay approximately four dollars (\$4.00) a day for a dose of Plavix.

- 26. Defendants' nearly eight-year run of lying to physicians and the public about the safety and efficacy of Plavix for the sole purpose of increasing corporate profits has now been uncovered by scientific studies that reveal that not only is Plavix not worth its high price—it is dangerous.
- and named for the scientific researcher who conducted it, showed the fallacy of Defendants' assertions that Plavix is safer and more effective for patients who have a gastrointestinal intolerance to aspirin. The Chan study compared the effects of Aspirin and Plavix on patients who had previously had stomach ulcers that had healed. In that group, the incidence of recurring stomach bleeding was 8.6% in the Plavix group versus only .7% in the aspirin group. Dr. Chan recommended that the prescribing guidelines for Plavix be changed so that patients would not erroneously believe that Plavix is safer on the stomach than aspirin.
- 28. The Chan study also uncovered the fact that an aspirin a day plus esomeprazole (the generic name for a cheap, over the counter proton pump inhibitor like Prilosec) is far more cost effective for the consumer than paying for a four-dollar (\$4.00) a-day Plavix pill that greatly increases the risk of stomach bleeding.
- 29. Most recently, the CHARISMA trial uncovered another truth about Plavix. It found that Plavix plus aspirin (dual therapy) is only minimally more effective than aspirin plus placebo at preventing atherothrombotic events. But more importantly, it found that in patients who do not have peripheral arterial disease (PAD) or acute coronary syndrome (ACS), Plavix plus aspirin (dual therapy) poses a 20% increased risk to the patient of suffering bleeding injuries, heart attacks, stroke and death. In other

words, in those patients without ACS or PAD, dual therapy with aspirin and Plavix does more harm than good.

- 30. Despite the growing body of scientific knowledge that the four-dollar (\$4.00) Plavix pill was not much better than a four-cent-a-day aspirin, Defendants kept promoting it to the public and to physicians, using hyperbole and outright falsification in the process.
- 31. In 2006, Mr. Dawkins was prescribed Plavix plus aspirin (dual therapy) to treat multiple cardiovascular risks. In July of 2006, Mr. Dawkins developed stomach pain which eventually necessitated hospitalization on or about August 31, 2006. Soon after his admission to the hospital, Mr. Dawkins became gravely ill and was taken to the intensive care unit where he remained in a coma for six days. Ultimately, Mr. Dawkins was hospitalized for seventeen days, during which time he required plasmapheresis to treat his TTP. Following his discharge, Mr. Dawkins suffered through a long convalescence and has permanent injuries due to the TTP caused by Plavix.

COUNT I

DEFECTIVE DESIGN

- 32. Plaintiff incorporates by reference, paragraphs 1 through 31, as if fully set forth.
- 33. At all times material to this action, the Defendants were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Plavix.
 - 34. Plavix is defective and unreasonably dangerous to consumers.

- 35. Plavix is defective in its design or formulation in that when it left the hands of the Defendants, its foreseeable risks exceeded the benefits associated with its design and formulation and/or it was more dangerous than an ordinary consumer would expect.
- 36. The foreseeable risks associated with the design or formulation of Plavix, include, but are not limited to, the fact that the design or formulation of Plavix is more dangerous than a reasonably prudent consumer would expect when used in an intended and reasonably foreseeable manner.
- 37. At all times material to this action, Plavix was expected to reach, and did reach, consumers in the State of Ohio and throughout the United States, including the Plaintiff, without substantial change in the condition in which it was sold.
- 38. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective, unreasonably dangerous condition, at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following:
- a) When placed in the stream of commerce, Plavix contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting the Plaintiff to risks that exceeded the benefits of Plavix, including but not limited to the risks of suffering avoidable heart attacks, strokes, blood disorders, abnormal bleeding and even death in an unacceptably high number of its users;
- b) When placed in the stream of commerce, Plavix was defective in design and formulation, making the use of Plavix more dangerous than an ordinary consumer

would expect, and more dangerous than other risks associated with the other similar drugs on the market including Aspirin;

- c) Plavix's design defects existed before it left the control of the Defendants;
- d) Plavix was insufficiently tested;
- e) Plavix caused harmful side effects that outweighed any potential utility; and
- f) Plavix was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including the Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff, individually and collectively.
- 39. In addition, at the time that Plavix left the control of the Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing Plavix's utility.
- 40. As a direct and proximate result of Plavix's defective design, the Plaintiff suffered the severe physical injuries and damages described in paragraph 31.
- 41. The Plaintiff has endured substantial pain and suffering, has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

- 42. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.
- 43. The Plaintiff's injuries and damages were severe and will continue into the future. For those reasons, the Plaintiff seeks actual and punitive damages from the Defendants.
- 44. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, warranting the imposition of punitive damages.

WHEREFORE, the Plaintiff, demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT II

MANUFACTURING DEFECT

- 45. Plaintiff incorporates by reference paragraphs 1 through 44 as if fully set forth.
- 46. At all times material to this action, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Plavix.
- 47. At all times material to this action, Plavix was expected to reach, and did reach consumers in the State of Ohio and throughout the United States, including the Plaintiff, without substantial change in the condition from which it was sold.

- 48. At all times material to this action, Plavix was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways that include, but are not limited to, one or more of the following particulars posing a serious risk of injury and death.
- a) When placed in the stream of commerce, Plavix contained manufacturing defects that rendered the product unreasonably dangerous;
- b) Plavix's manufacturing defects occurred while the product was in the possession and control of the Defendants;
- c) Plavix was not made in accordance with the Defendants' product specifications or performance standards; and,
- d) Plavix's manufacturing defects existed before it left the control of the Defendants.
- 49. As a direct and proximate result of Plavix's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries.
- 50. The Plaintiff has endured substantial pain and suffering. He has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.
- 51. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

- 52. The Plaintiff's injuries and damages were severe; are permanent and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.
- 53. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT III

FAILURE TO WARN

- 54. Plaintiff incorporates by reference paragraphs 1 through 53 as if fully set forth.
- 55. Plavix was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff and/or her health care providers, of the dangerous risks and reactions associated with Plavix, including but not limited to its propensity to cause avoidable strokes, heart attacks, abnormal bleeding and other serious injuries and side effects despite the Defendants' knowledge of the increased risk of these injuries over other similar drugs such as aspirin.
- 56. Plavix was defective due to inadequate post-marketing warning or instruction because after Defendants knew or should have known of the risk of serious bodily harm and/or death from the use of Plavix, Defendants failed to provide an

adequate warning to consumers and/or their health care providers of the product, knowing the product could cause serious injury and/or death.

- 57. The Plaintiff was prescribed and used Plavix for its intended purpose.
- 58. The Plaintiff could not have discovered any defect in Plavix through the exercise of reasonable care.
- 59. The Defendants, as manufactures and/or distributors of Plavix are held to the level of knowledge of an expert in the field.
- 60. The warnings that were given by the Defendants were not accurate, clear, or complete, and/or were ambiguous.
- 61. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks of stroke, heart attack, bleeding, and other serious injuries and side effects, and failed to instruct physicians to test and monitor for the presence of the injuries for which Plaintiff and others had been placed at risk.
- 62. The warnings that were given by the Defendants failed to properly warn consumers of the increased risks of stroke, heart attack, bleeding, and other serious injuries and side effects.
- 63. The Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of the Defendants. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with Plavix. Had the Plaintiff received adequate warnings regarding the risks of Plavix, he would not have used it.

- 64. As a direct and proximate result of Plavix's defective and inappropriate warnings, the Plaintiff suffered severe physical injuries and damages, as described in paragraph 31.
- 65. As a direct and proximate result of Plaintiff's use of Plavix, Plaintiff has endured substantial pain and suffering; has incurred significant expense for medical care and treatment, and will continue to suffer and incur such expenses in the future.
- 66. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.
- 67. The Plaintiff's injuries and damages are permanent and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.
- 68. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, warranting the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT IV

NEGLIGENCE

69. Plaintiff incorporates by reference paragraphs 1 through 68 as if fully set forth.

- 70. At all material times, the Defendants, and each of them individually, had a duty to exercise reasonable care to consumers, including the Plaintiff, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Plavix into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events.
- 71. The Defendants, and each of them individually, breached their duty of reasonable care to the Plaintiff in that they negligently designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and/or sold Plavix.
- 72. The Plaintiff's injuries and damages suffered are the direct and proximate result of the carelessness and negligence of the Defendants in failing to exercise ordinary care in at least the following ways:
- a) In its design, development, research, manufacture, testing, packaging, promotion, marketing, sale and/or distribution of Plavix;
- b) In its failure to warn or instruct, and/or adequately warn or adequately instruct users of Plavix, including Plaintiff herein, of Plavix's dangerous and defective characteristics;
- c) In its design, development, implementation, administration, supervision, and/or monitoring of clinical trials for Plavix;
- d) In its promotion of Plavix in any overly aggressive, deceitful and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause serious injury and/or death;

- e) In representing that Plavix was safe for its intended use when, in fact, Plavix was unsafe for its intended use;
 - f) In failing to perform appropriate pre-market testing of Plavix;
 - g) In failing to perform appropriate post-market testing of Plavix; and
 - h) In failing to perform appropriate post-market surveillance of Plavix.
- 73. The Defendants knew or should have known that consumers such as the Plaintiff would suffer injury as a result of the Defendants' failure to exercise reasonable and ordinary care.
- 74. Despite the fact that Defendants knew or should have known that Plavix posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Plavix for use by consumers.
- 75. As a direct and proximate result of Defendants' misrepresentations, carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries and damages as described in paragraph 31.
- 76. The Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.
- 77. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.
- 78. The Plaintiff's injuries and damages were severe, are permanent and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.

79. Defendants' conduct as described above, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT V

NEGLIGENT MISREPRESENTATION

- 80. Plaintiff incorporates by reference paragraphs 1 through 79 as if fully set forth.
- 81. Defendants, having undertaken the manufacturing, marketing, distribution, and/or promotion of Plavix, owed a duty to provide accurate and complete information regarding Plavix.
- 82. Defendants falsely represented to Plaintiff in direct to consumer advertising and indirectly through misrepresentations to the prescribing physician, that Plavix was safe and effective. The representations by Defendants were in fact false and Plavix was not safe and was in fact dangerous to Plaintiff's health.
- 83. At the time the representations were made, Defendants concealed from Plaintiff and Plaintiff's prescribing physician information about the propensity of Plavix to cause great harm.
- 84. Defendants negligently misrepresented claims regarding the safety and efficacy of Plavix despite the lack of information of the representations' accuracy.
- 85. Defendants' misrepresentations were made by Defendants with the intent to induce Plaintiff to use Plavix, to Plaintiff's detriment.

- 86. At the time of Defendants' misrepresentations and omissions, Plaintiff and Plaintiff's physician were ignorant of the falsity of these statements and reasonably believed them to be true.
- 87. Defendants represented and marketed Plavix as being safe and effective. After Defendants became aware of the risk of ingesting Plavix, however, Defendants failed to communicate to Plaintiff and/or the general public that the ingestion of this drug could cause a person serious and potentially fatal bodily injury.
- 88. Plaintiff brings this cause of action against Defendants under the theory of negligent misrepresentation for at least the following reasons:
- a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;
- b) Defendants failed to warn Plaintiff and other consumers of the defective condition of Plavix as manufactured and/or supplied by Defendants;
- c) Defendants individually and through their agents, representatives, distributors, and/or employees negligently misrepresented material facts about Plavix in that they made such representations when they knew or reasonably should have known of the falsity of such misrepresentations; or alternatively, Defendants made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations
- 89. Defendants' misrepresentations were made with the intention to influence consumers, like Plaintiff and in order to avoid losses and sustain profits in its sales to consumers.

- 90. Defendants' misrepresentations were made to Plaintiff, as well as the general public. Plaintiff and Plaintiff's healthcare provider justifiably relied on Defendants' misrepresentations and consequently, Plaintiff's ingestion of Plavix was to Plaintiff's detriment.
- 91. Defendants' misrepresentations proximately caused Plaintiff's injuries, damages and monetary losses.
- 92. As a direct and proximate result of Defendants' carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries and damages, as described in paragraph 31.
- 93. The Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.
- 94. The Plaintiff has lost past earnings and has suffered a loss of earning capacity; has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.
- 95. The Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, Plaintiff seeks actual and punitive damages from the Defendants.
- 96. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VI

VIOLATIONS OF OHIO CONSUMER SALES PRACTICES ACT

- 97. Plaintiff incorporates by reference paragraphs 1 through 96 as if fully set forth.
- 98. The Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of Plavix.
- 99. The Defendants knew or should have known, that Plavix was unreasonably dangerous and defective, and had a propensity to cause serious and potentially life threatening side effects.
- 100. Despite their knowledge, the Defendants omitted material facts in the disclosures they made to the public, the medical community and to consumers, including the Plaintiff, concerning the use and safety of Plavix.
- 101. The Defendants have violated the Ohio Consumer Sales Practices Act ("OCSPA"), in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff, concerning the use and safety of Plavix.
- 102. The Defendants' practices relating to their promotion of Plavix created and/or reinforced a false impression as to its safety.
- 103. The Defendants' practice of promoting Plavix placed and continues to place all consumers of Plavix at risk for serious injury and potentially lethal side effects.

- 104. The Defendants' statements and omissions were made with the intent that the Plaintiff, and Plaintiff's prescribing physician, would rely on them.
- 105. The Plaintiff purchased and used Plavix for personal, family or household purposes and suffered ascertainable losses of money as a result of the Defendants' use or employment of the methods, acts, or practices.
- 106. Defendants' promotion, statements and/or omissions concerning Plavix constitute unconscionable commercial practices, deceptions, false pretenses, misrepresentations, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon the concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by Defendants, in violation of the Ohio Consumer Sales Practices Act ("OCSPA")
- 107. As a direct and proximate cause of the Defendants' acts of consumer fraud, the Plaintiff has suffered ascertainable loss-economic loss that includes the purchases of Plavix and additional out-of-pocket healthcare related costs, for which the Defendants are liable to the Plaintiff for treble Plaintiff's actual damages.
- 108. As a direct and proximate cause of the Defendants' acts of consumer fraud, the Plaintiff further suffered severe and permanent physical injuries.
- 109. The Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.
- 110. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.

111. The Plaintiff's injuries and damages are severe and permanent, and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

COUNT VII

PUNITIVE DAMAGES

- 112. Plaintiff incorporates by reference paragraphs 1 through 111, as if fully set forth.
- 113. At all material times, the Defendants knew or should have known that Plavix was inherently more dangerous than aspirin with respect to the risk of bleeding injuries, heart attacks, stroke and death.
- 114. At all material times, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of Plavix.
- 115. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff, concerning the safety of Plavix.
- 116. At all material times, the Defendants knew and recklessly disregarded the fact that Plavix causes debilitating and potentially lethal side effects with greater frequency than safer alternative drugs, such as aspirin.

- 117. Despite their knowledge, the Defendants continued to aggressively market Plavix to consumers, including Plaintiff, without disclosing the lethal side effects when there were safer alternatives such as aspirin.
- 118. The Defendants knew of Plavix's defective and unreasonably dangerous nature, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff, in conscious and/or negligent disregard of the foreseeable harm caused by Plavix.
- 119. Defendants intentionally concealed and/or recklessly failed to disclose to the public, including the Plaintiff, the potentially life threatening side effects of Plavix in order to ensure continued and increased sales.
- 120. The Defendants' intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable Plaintiff to weigh the true risks of using Plavix against its benefits.
- 121. Plaintiff is entitled to punitive damages because the Defendants' failure to warn was reckless, without regard for the public's safety and welfare and constituted a flagrant disregard for human life. The Defendants misled both the medical community and the public at large, including the Plaintiff, by making false representations about the safety of Plavix. Defendants downplayed, understated and/or disregarded its knowledge of the serious and permanent side effects and risks associated with the use of Plavix despite available information demonstrating that Plavix was likely to cause serious and even fatal side effects to users. Defendants' actions and/or inactions were willful and wanton.

- 122. Defendants were or should have been in possession of evidence demonstrating that Plavix caused serious side effects. Nevertheless, Defendants continued to market Plavix by providing false and misleading information with regard to safety and efficacy. Defendants failed to provide warnings that would have dissuaded physicians from prescribing Plavix and consumers from purchasing and consuming Plavix, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Plavix.
- 123. As a direct and proximate result of the Defendants' conscious and deliberate, flagrant disregard for human life and the rights and safety of consumers, such as Plaintiff, the Plaintiff suffered severe and permanent physical injuries and damages, as described in paragraph 31.
- 124. The Plaintiff has endured substantial pain and suffering; has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future.
- 125. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured.
- 126. The Plaintiff's injuries and damages are severe, permanent and will continue into the future. As a result, the Plaintiff seeks actual and punitive damages from the Defendants.
- 127. Defendants' conduct was committed with knowing, conscious and deliberate, flagrant disregard for human life and the rights and safety of consumers,

including the Plaintiff, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff prays for judgment against each of the Defendants as follows:

- a) Awarding actual damages to the Plaintiff incidental to Plaintiff's purchase and use of Plavix in an amount to be determined at trial;
- b) Awarding Plaintiff's compensatory damages against Defendants in an amount sufficient to fairly and completely compensate Plaintiff for all damages;
- c) Awarding Plaintiff treble damages against Defendants so as to fairly and completely compensate Plaintiff for all damages, and to deter similar wrongful conduct in the future;
- d) Awarding Plaintiff punitive damages against Defendants in an amount sufficient to punish Defendants for their wrongful conduct and to deter similar wrongful conduct in the future consistent with applicable law;
- e) Awarding pre-judgment and post-judgment interest to the Plaintiff;
- f) Awarding the costs and expenses of this litigation to Plaintiff;
- g) Awarding reasonable attorney's fees and costs to the Plaintiff as provided by law; and,

h) Granting all such other and further relief as the Court deems necessary, just and proper.

Respectfully submitted,

THE MILLER FIRM, LLC

Michele A DiMartino

DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Huckel U. Offazera Michele A. DiMartino, Esquire

Dated: May 1, 2009

CERTIFICATION PURSUANT TO LOCAL RULE 11.2

The undersigned attorney for the Plaintiff certifies that the matter in controversy is not the subject of any other action pending in any Court or of a pending arbitration or administrative proceeding.

I certify that the foregoing statement made by me is true to the best of my knowledge, information and belief. I am aware that if the foregoing statement made by me is willfully false, I am subject to punishment.

Michele A. DiMartino, Esquire

Dated: May 1, 2009

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A., 56:8-20, Plaintiff is mailing a copy of this Complaint and Jury Demand to the Office of Attorney General, Cn-006, Trenton, New Jersey, within (10) days of the filing of this Complaint and Jury Demand.

Michele A. DiMartino, Esquire

Dated: May 1, 2009

MICHAEL J. MILLER, ESQ.* CHRISTOPHER A. GOMEZ, ESQ.* THE MILLER FIRM, LLC The Sherman Building 108 Railroad Avenue Orange, VA 22960

NANCY HERSH, ESQ., State Bar No. 49091*
MARK E. BURTON, JR., ESQ., State Bar No. 178400*
CHARLES C. KELLY, II, ESQ., State Bar No. 122253*
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue
2080 Opera Plaza
San Francisco, CA 94102-6388
(415) 441-5544

Attorneys for Plaintiffs
* Admission Pro Hac Vice To Be Filed